Appendix A - World Health Organization Trial Registration Data Set

Data category	**Information**[32]
Primary registry and trial identifying number	ClinicalTrials.gov NCT05416229
Date of registration in primary registry	June 8, 2022
Secondary identifying numbers	The Regional Committee on Research Ethics (journal number H-20043832) and the Danish Medicines Agency (EudraCT 2020-000829-55)
Source(s) of monetary or material support	The Novo Nordisk Foundation, The Ivan Nielsen Foundation, The Lundbeck Foundation and The Health Foundation
Primary sponsor	The Novo Nordisk Foundation
Secondary sponsor(s)	The Ivan Nielsen Foundation, The Lundbeck Foundation and The Health Foundation
Contact for public queries	Mathias Ebbesen Jensen MD, Psychiatric Centre Copenhagen, Rigshospitalet, Copenhagen University Hospital, Denmark
Contact for scientific queries	Mathias Ebbesen Jensen MD, Psychiatric Centre Copenhagen, Rigshospitalet, Copenhagen University Hospital, Denmark Anders Fink-Jensen MD, DMSc, Psychiatric Centre Copenhagen, Rigshospitalet, Copenhagen University Hospital, Denmark
Public title	Psilocybin-assisted Therapy for Alcohol Use Disorder
Scientific title	Study protocol for the QUANTUM Trip Trial – Psilocybin-assisted therapy for reducing alcohol intake in patients with alcohol use disorder: a randomised, double-blinded, placebo-controlled 12-week clinical trial

Data category	**Information**[32]
Countries of recruitment	Denmark
Health condition(s) or problem(s) studied	Alcohol Use Disorder
Intervention(s)	Active comparator: Psilocybin 25 mg, a single administration, per os. Placebo comparator: lactose (opaque matching capsules containing no active ingredient)
Key inclusion and exclusion criteria	Inclusion criteria - Age of 20-70 years (both included). - Weight 60-95 kg (both included) - Diagnosed with AUD according to DSM-5 criteria and alcohol dependence according to ICD-10. - Alcohol Use Disorder Identification Test (AUDIT) ≥ 15. - ≥ 5 heavy drinking days. Exclusion criteria - Personal or first-degree relatives with current or previous diagnosis within psychotic spectrum disorders or bipolar disorder. - Pharmacotherapy against AUD including disulfiram, naltrexone, acamprosate and nalmefene or treatment with any of these compounds within 28 days prior to inclusion. - Treatment with any serotonergic medication or any use of serotonergic psychedelics within 1 month prior to inclusion.
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: double blind (subject, caregiver, investigator, outcomes assessor) Primary purpose: treatment efficacy Phase II

Data category	**Information**[32]
Date of first enrolment	August 2022 (anticipated)
Target sample size	90
Recruitment status	Not yet recruiting
Primary outcome(s)	The primary outcome is the difference between the two treatment arms with respect to change from baseline to Week 12 (visit 8) in percent heavy drinking days, defined as days within the last 28 days with five drinks/60 grams of alcohol or more for men, four drinks/48 grams for women. Data will be collected using the Timeline Followback Method (TLFB).
Key secondary outcomes	- Alcohol consumption (gram/day) as measured by TLFB - Percent days of abstinence as measured by TLFB - Biological markers of alcohol consumption as measured by blood phosphatidyl-ethanol (PEth), gamma-glutamyltransferase (GGT), alanine aminotransferase (ALAT) and mean corpuscular volume (MCV). - Self-reports as measured by mean scores in the questionnaires assessing alcohol craving, self-efficacy depressive symptoms, quality of life, mindfulness, psychological flexibility, and personality traits. - Pharmakokinetics of plasma psilocin, the active metabolite of psilocybin. - Neuronal response to alcohol cues and cognitive flexibility within cortico-striatal pathways by use of functional magnetic resonance brain imaging one week post dosing.